

## **REMARKS**

Reconsideration of the application is respectfully requested. In light of the comments which follow, it is believed that all issues are removed and that this application is in condition for passage to allowance.

### ***Status of All of the Claims***

Upon entry of this response, the status of the claims will be as follows:

1. Claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 45-54 will be pending and under consideration.
2. Claims 3, 33-37 and 41 have been withdrawn.
3. Claims 1, 4-9, 12, 15-25 and 43-44 have been cancelled.

### ***Support for amendments / new claims***

Support for an array being more than two vessel wall-penetrating elements wide can be found, for example, at page 12, lines 29-30 of the PCT application. Support for a first piece of flexible material having an intermediate region that extends inwardly of peripheral edges of the first piece of flexible material can be found throughout the application including in Figure 2 and its associated text. Support for a first piece of flexible material having a first edge and a second edge with the second edge being generally opposite the first edge is supported by Figure 2 and its associated text. This disclosure further supports a second array of vessel wall-penetrating elements extending longitudinally proximate the second edge of the first piece of flexible material with the second array having a width extending in a direction inward of the second edge and having vessel wall-penetrating elements occurring generally laterally with respect to one

another in the direction of the width of the second array, and driving vessel wall-penetrating elements of the second array into the wall of the vascular vessel so as to secure a corresponding second band of the first piece of flexible material to the vascular vessel wall.

### ***Interview Summary***

The undersigned attorney would again like to thank examiner Sharma for the courtesy of the October 13, 2010, telephone interview. The interview included a discussion of the Pavcnik and Lucatero references. An agreement on allowable subject matter was not reached. Rather, examiner Sharma stated that she would consider any amendments when filed as part of a Request for Continued Examination, and indicated that prior to any next action she would be willing to work with the undersigned attorney to try to arrive at agreeable claim language.

### ***Claim Rejections – 35 U.S.C. § 112***

Claim 14 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent maintained, this rejection is respectfully traversed.

It is very possible, and well supported by the original disclosure, for a barb to both penetrate a piece of material, and while penetrating the material, to extend from the material. Such an arrangement is supported, for example, by paragraph [0033].

### ***Claim Rejections – 35 U.S.C. § 103***

Claims 2, 10, 11, 14, 26-32, 38-40 and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in

view of Lucatero et al. (2004/0087975) "Lucatero". To the extent maintained, this rejection is respectfully traversed.

As clearly shown in Figure 4, Lucatero teaches a coaptation device that is used to pull together and connect the middle regions of opposing, native leaflets in a bicuspid valve. Proximal elements 16 are a short, fat, clamp-like members, and in combination with distal elements 18, are used to capture native valve leaflets for drawing them together for coaptation purposes.

Pavcnik discloses nothing of the sort, especially in Figure 43 which depicts a thin, resilient wire frame that has a series of bends and interconnecting sides and is transformable into a generally serpentine shape as shown. Pavcnik's barbs are generally used to anchor the device (e.g., an artificial valve) along the vessel wall upon implantation. Pavcnik's barbs are not used to grip the middle regions of native valve leaflets for drawing them together for coaptation purposes as taught by Lucatero.

If it is the Patent Office's position that it would have been obvious to take the design of Lucatero's component (16) and use it to construct the entirety of Pavcnik's frame, Applicants cast serious doubt on the real-world suitability of making this substitution, and seek clarification on exactly what teaching from Lucatero would have convinced a person of ordinary skill in the art that (i) the short, fat, clamp-like member (16) could be suitably transformed into a compressible-expandable, serpentine-shaped frame as taught by Pavcnik; and (ii) the result of this proposed modification was predictable -- that the modified Pavcnik frame would function in all respects as intended by Pavcnik.

Given the many performance characteristics sought by Pavcnik for his compressible-expandable, serpentine-shaped frame (e.g., delivery, deployment, post-deployment function), and

given the unpredictability of even trying to fabricate Pavcnik's frame from the short, fat, clamp-like member (16) in Lucatero, Applicants respectfully contend that the ordinarily-skilled person would not have even attempted this substitution.

On the other hand, if it is the Patent Office's position that it would have been obvious to take only the barbs (60) from Lucatero's clamp-like member and transplant them onto Pavcnik's frame, Applicants question how this single component can be conveniently plucked from Lucatero to support a 103 rejection when according to well established principle, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965).

If the Patent Office proceeds on this basis, Applicants respectfully contend that it would be doing all of the following:

- (i) borrowing from a coaptation device reference (Lucatero) that teaches nothing about anchoring a compressible-expandable, serpentine-shaped frame along a vessel wall;
- (ii) looking only at one part of Lucatero's device -- proximal element (16) -- to the exclusion of all other components necessary to the intended function of his device; and
- (iii) extracting only the barbs (60) from proximal element (16) to the exclusion of all other parts of the proximal element necessary to its intended function.

For at least these reasons, a person of ordinary skill in the art would not have modified Pavcnik in view of Lucatero as proposed by the Patent Office, and thus a *prima facie* case of obviousness has not been established with respect to any of claims 2, 10, 11, 14, 26-32, 38-40 or 42. Withdrawal of these rejections is therefore solicited.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero" further in view of Ahn (5,843,170). To the extent maintained, this rejection is respectfully traversed.

Ahn does not cure any of the above-described deficiencies in the proposed Pavcnik-Lucatero combination, and thus the stated rejection does not render claim 13 obvious. For at least this reason, withdrawal of this rejection is solicited.

Claim 45-47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero" further in view of Dobben (4,994,077). To the extent maintained, this rejection is respectfully traversed.

Dobben does not cure any of the above-described deficiencies in the proposed Pavcnik-Lucatero combination, and thus the stated rejection does not render any of claims 45-47 obvious. For at least this reason, withdrawal of these rejections is solicited.

Claim 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al.

(2004/0087975) "Lucatero" further in view of Yang (2002/0138138). To the extent maintained, this rejection is respectfully traversed.

Yang does not cure any of the above-described deficiencies in the proposed Pavcnik-Lucatero combination, and thus the stated rejection does not render any of claims 48-50 obvious. For at least this reason, withdrawal of these rejections is solicited.

With regard to new claim 53, none of the cited references, alone or in combination, teach an array as claimed being more than two vessel wall-penetrating elements wide.

### **Conclusion**

In view of the foregoing, it is believed that the claims are in condition for allowance, and action to that end is solicited. The Examiner is invited to telephone the undersigned attorney to resolve any outstanding matters concerning the present application. It should be understood that the claim amendments are made without prejudice or admission in respect of the previously claimed subject matter or remarks in the Office Action, and that the above remarks are not intended to provide an exhaustive basis for patentability or to concede any basis for the rejections in the Office Action but are provided to address the rejections made in the Office Action in an expedient fashion.

### **Request for Interview**

The Applicant requests an opportunity for an interview of the Examiner if the Examiner believes that any objection or rejection could be maintained against the application as amended.

The Examiner is requested to contact the undersigned attorney to arrange any such interview necessary.

Respectfully submitted,

By



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